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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,324	07/13/2001	Shizuo Akira	31671-173143	2302

26694 7590 09/22/2004

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/889,324	<b>Applicant(s)</b> AKIRA ET AL.	
	<b>Examiner</b> Celine X Qian	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8,9 and 12-58 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 12-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 8, 9, 12-58 are pending in the application. Claims 8, 9, 12-51 are withdrawn from consideration for being directed to non-elected subject matter. Claims 52-58 are currently under examination.

This Office Action is in response to the Amendment filed on 7/1/04.

#### ***Response to Amendment***

The rejection of claims 1-7 under 35 U.S.C. 112 1<sup>st</sup> paragraph is moot in light of Applicant's cancellation of the claims.

The objection to claims 5-7 is moot in light of Applicant's cancellation of the claims.

The newly added claims 52-58 are rejected under 35 U.S.C. 112 1<sup>st</sup> paragraph for reasons discussed below.

#### ***New Grounds of Rejection***

##### ***Claim Rejections - 35 USC § 112***

Claims 52-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mouse comprising homozygous disruption of TLR2 gene in its genome, wherein such disruption results in no production of endogenous TLR2 protein, and wherein said mouse exhibits the phenotype of being unresponsive to bacterial cell components that is a lipoprotein/lipopeptide, and further unresponsive to peptidylglycan, and hyporesponsive to cell wall fraction of Gram positive bacteria; and a mouse comprising homozygous disruption of MyD88 gene in its genome, wherein such disruption results in no production of endogenous MyD88 protein, and wherein said mouse exhibits the phenotype of being unresponsive to bacterial cell components that is a lipoprotein/lipopeptide, and further unresponsive to

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peptidylglycan, lipoteichoic acid, Mycobacterium tuberculosis lysate, and hyporesponsive to cell wall fraction of Gram negative bacteria; does not reasonably provide enablement for a mouse comprising homozygous disruption of TLR2 or MyD 88 gene in its genome, wherein such disruption results in no production of endogenous MyD88 or TLR2 protein, and wherein said mouse exhibits the phenotype of being unresponsive to bacterial cell components that is a lipoprotein/lipopeptide, and further unresponsive to peptidylglycan, endotoxin, lipoteichoic acid, Mycobacterium tuberculosis lysate, and hyporesponsive to cell wall fraction of Gram positive bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The claims are drawn to a mouse comprise either homozygous disruption of TLR2 or MyD88 that is unresponsive to a number of bacterial cell components including lipoprotein/lipopeptide, peptidylglycan, endotoxin, lipoteichoic acid and Mycobacterium tuberculosis and hyporesponsive to cell wall fraction of Gram positive bacteria. However, based on the disclosure of the specification, the mouse having homozygous disruption of endogenous TLR2 exhibits the phenotype of being unresponsive to bacterial cell components that is a lipoprotein/lipopeptide, and further unresponsive to peptidylglycan, and hyporesponsive to cell wall fraction of Gram positive bacteria. The mouse having homozygous disruption of endogenous MyD88 gene exhibits the phenotype of being unresponsive to bacterial cell components that is a lipoprotein/lipopeptide, and further unresponsive to peptidylglycan, lipoteichoic acid, Mycobacterium tuberculosis lysate, and hyporesponsive to cell wall fraction of Gram negative bacteria. According to such disclosure, the two mice have different phenotype

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depends on which gene is disrupted even though some of the phenotype overlaps. Nevertheless, each mouse has distinct phenotypic feature of its own. As discussed in the previous office action, the phenotype of the mouse is essential characteristic for the enablement of the claimed mouse. As such, the specification is not enabling for a mouse that has a disruption in one gene but exhibits the phenotype of another. Therefore, the claimed invention is only enabled to the scope indicated above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

DAVE T. NGUYEN  
PRIMARY EXAMINER

